REMARKS

Reconsideration of the application is respectfully requested.

The listing of claims presented herein amends claims 21 and 25-29, cancels claims 22-24 and 31-38 without prejudice to or disclaimer of the subject matter of the cancelled claims. Applicants reserve the right to prosecute claims directed to the subject matter of claims 33-38 in divisional and/or continuation applications. The amendment to claim 21 and addition of new claims 39 and 45 divides the subject matter of independent claim 21 into three independent claims. New claims 40-43 and 46-49 correspond to claims 25-28. New claim 44 corresponds to cancelled claim 31 and new claim 50 corresponds to cancelled claim 32. No new matter enters by amendment. With entry of this amendment, claims 21, 25-29, and 39-50 are pending in this application.

Amended claim 21 and new claims 39 and 45 recite "A purified antibody that binds with HIV-2 gp300 and does not bind with HIV-2 gp140" (claim 21); "A purified antibody that binds with HIV-2 p200 and does not bind with HIV-2 gp140" (claim 39); and "A purified antibody that binds with HIV-2 p90/80 and does not bind with HIV-2 gp140" (claim 45). This claim language is supported by Applicants' specification, as described in the Declaration of Jacques H. M. Cohen, M.D., Ph.D. Under 37 C.F.R. § 1.132, a copy of which is attached hereto as Exhibit A.

At page 4, line 21 to page 5, line 9, the application states:

> Four glycoproteins of apparent molecular weights 300,000, 140,000, 125,000, and 36,000 daltons (gp300, gp140, gp125, and gp36) are detectable in human immunodeficiency virus type 2 (HIV-2) infected cells. The gp125 and gp36 are the external and transmembrane components, respectively, of the envelope glycoproteins of HIV-2 mature virions. It has now been discovered that the

> gp300 is a dimeric form of gp140, which is the precursor of HIV-2 envelope glycoprotein. This invention thus provides gp300 glycoprotein of HIV-2 and human retroviral variants of HIV-2 in purified form.
>
> This invention also provides proteins of HIV-2 or of a human retroviral variant of HIV-2 having apparent molecular weights of about 200 Kd (p200) and about 90 to about 80 Kd (p90/80). These proteins are substantially unglycosylated and are in a purified form.

Dr. Cohen, one of skill in the art, understands this passage as describing newly identified, purified gp300, p200, and p90/80 proteins of HIV-2 as a subject of the invention described in the application. (Exhibit A at ¶ 12.) Because this passage makes reference to the gp140 protein of HIV-2, but does not refer to it as part of the invention, Dr. Cohen also understands this passage to mean that the gp140 protein is not a subject of the invention described in the application. (Exhibit A at ¶ 12.)

Original claim 3, at page 58, lines 11-13 of the application as filed, described:

> 3. An isolated antibody which binds with a protein selected from the group consisting of gp300 of HIV-2, p200 of HIV-2, p90/80 of HIV-2, and $gp300_{SIV}$.

Original claim 3 is part of the written description of the application. *See In re Koller*, 613 F.2d 819, 204 U.S.P.Q. 702 (CCPA 1980). Dr. Cohen understands this passage as describing antibodies, which bind with the newly identified, purified gp300, p200, and p90/80 proteins of HIV-2 as a further subject of the invention described in the application. (Exhibit A at ¶ 14.) Because the application makes reference to the gp140 protein of HIV-2, but does not refer to it as part of the invention, and because the application specifically states that the antibodies described in the application bind with a protein selected from gp300 of HIV-2, p200 of HIV-2, and p90/80 of HIV-2, without mentioning binding with gp140 of HIV-2, Dr. Cohen understands this passage (i.e.,

original claim 3) as describing antibodies that bind with gp300 of HIV-2, p200 of HIV-2, and/or p90/80 of HIV-2, but not with gp140 of HIV-2. (Exhibit A at ¶ 14.)

Dr. Cohen's understanding of the meaning of the passages of the application described above was consistent with what was known in 1994 regarding neoantigens, present in molecular complexes but absent from the components of the complexes when in free form, and capable of being recognized by specific antibodies. For example, at paragraphs 15 and 16 of Exhibit A Dr. Cohen describes studies showing that specific antibodies had been generated that bound to neoantigens that are present in the terminal complement complex (TCC) but are absent from the molecular components of the TCC in their free form. Dr. Cohen understands these studies as showing that antibodies to the neoantigen are necessarily able to bind to the protein complex that contains the neoantigen but not to the components of the complex when in free form. (Exhibit A at ¶ 17.) For this additional reason, Dr. Cohen stated that he "understand[s] today and would have understood in 1994 that the antibodies of the invention are antibodies that bind with gp300 of HIV-2, p200 of HIV-2, and/or p90/80 of HIV-2, but not with gp140 of HIV-2." (Exhibit A at ¶ 17.) Dr. Cohen further concluded that "[b]ecause gp300 is a dimeric form of gp140, [he understands] today and would have understood in 1994 that these antibodies distinguish between the dimeric gp300 complex and the gp140 monomer by binding to a neoantigen present on the gp300 complex but absent from the gp140 monomer." (Exhibit A at ¶ 17.)

The Pending Claims Are Novel and Nonobvious

The Examiner rejected claims 21-24 and 27-29, 31, and 32 as allegedly anticipated by Montagnier *et al.* (1997) as evidenced by Walsh et al. (1985), Earl et al. (1990), and McGuire *et al.* (1992). (Office action at pages 1-4.) The Examiner acknowledges that Montagnier does not literally disclose antibodies that bind with HIV-2 gp300, p200, or p90/80. However, the Examiner contends that antibodies that bind with HIV-2 gp140, as disclosed in Montagnier, would inherently also bind with HIV-2 gp300, which is a gp140 dimer, with p200, which is an unglycosylated form of the gp300 dimer, and with p90/p80, which is an unglycosylated form of gp140. This rejection is moot as to claims 22-24, 31, and 32 by cancellation of these claims. Applicants traverse this rejection as to claims 21, and 27-29, and submit that it should not be applied to the new claims.

The amended/new claims explicitly exclude antibodies that bind with gp140. Specifically, the amended/new claims are limited to antibodies that bind with HIV-2 gp300 and do not bind with HIV-2 gp140, antibodies that bind with HIV-2 p200 and do not bind with HIV-2 gp140, and antibodies that bind with HIV-2 p90/80 and do not bind with HIV-2 gp140. These claims precisely exclude the antibodies of Montagnier from their scope, in accordance with the written description in Applicants' specification. The Office has previously relied on alleged inherent features of the antibodies of Montagnier to reject Applicants' claims. However, Montagnier's antibodies that bind with gp140 can not inherently simultaneously possess the property of not binding with gp140. For this reason Montagnier does not disclose every element of the amended/new claims. Accordingly, the rejection for anticipation over Montagnier should be withdrawn. *See*

Verdegaal Bros v. Union Oil Co. of Calif., 814 F.2d 628, 631 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found either expressly or inherently in a single prior art reference."); *see also* M.P.E.P. § 2131.

The Office rejected claims 25 and 26 under 35 U.S.C. § 103(a) as allegedly obvious over Montagnier *et al.* (1997) in view of Galfrè and Milstein (1975). (Office Action at pages 4-5.) The Office cites Galfrè and Milstein as "provid[ing] detailed methodologies for labeling antibodies to facilitate their use in immunodiagnostic assays." (Office Action at page 5.) However, as described above, Montagnier does not disclose antibodies that bind with HIV-2 gp300 and do not bind with HIV-2 gp140, antibodies that bind with HIV-2 p200 and do not bind with HIV-2 gp140, and antibodies that bind with HIV-2 p90/80 and do not bind with HIV-2 gp140, as required by the amended/new claims. Nothing in Galfrè and Milstein remedies this deficiency. Accordingly, the amended/new claims are nonobvious over Montagnier in view of Galfrè and Milstein. Withdrawal of this rejection is respectfully requested.

The Office also rejected claims 33-38 under 35 U.S.C. § 102(e) or § 103(a). These claims have been cancelled herein, rendering these rejections moot. Withdrawal of these rejections in respectfully requested.

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims 21, 25-29, and 39-50.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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